DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

2129 CR 2 2128

APR 27 2004

Gensia Sicor Pharmaceuticals, Inc.
Attention: Rosalie Lowe
19 Hughes
Irvine, CA 92618-1902

Docket No. 02P-0245/CP1

Dear Ms. Lowe:

This letter is to inform you that the approval of your suitability petition for Fludarabine Phosphate Injection, 25 mg/mL, 2 mL vials, is hereby reinstated. We reference our letter suspending the approval of your petition dated February 11, 2004, and your waiver request dated February 11, 2004.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain an assessment of the safety and effectiveness of the drug for the claimed indication in relevant pediatric subpopulations unless the requirement is waived or deferred. This ANDA suitability petition was reviewed under PREA and the waiver has been granted.

If you have any questions regarding these requirements, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 301-827-5845.

Sincerely,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

02P-0245

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